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In re Application of:
MEISSNER ET AL.
Serial No.: 09/393,023
Filed: September 09, 1999
For: Human Criptin Growth Factor

DECISION ON PETITION

This is a decision on the petition under 37 CFR 1.144, filed March 27, 2002, to withdraw the restriction requirement.

On December 13, 2000, a restriction requirement was mailed to applicants. On May 17, 2001, applicants elected an invention with traverse, canceled claims 1-13, 15, and 17-18, and added new claims 21-95. On July 6, 2001, another restriction requirement was mailed to applicants in view of the many new claims added by the May 17, 2001 paper. On September 5, 2001, applicants again elected an invention with traverse. On November 26, 2001, a non-final Office action was mailed to applicants that rebutted applicants' traversal of the restriction requirement and made the restriction final. On March 27, 2002, the present petition was filed.

Petitioner asserted that the restriction requirement is improper because the examiner failed to consider whether the claimed inventions were "independent" as required by the plain and unambiguous meaning of 35 U.S.C. § 121. Specifically, petitioner urged that 35 U.S.C. § 121 says (emphasis added):

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.

From this, petitioner concluded that while the examiner presented reasons why the inventions are "distinct", the examiner did not present any reasons why the inventions were "independent" and, therefore, the examiner did not meet the statutory requirement for restriction.

Such an argument is not persuasive. The MPEP makes it clear that the USPTO interprets the "independent and distinct" language of the statute in such a way that restriction is proper as long as the inventions are independent or as long the inventions are distinct. In other words, the

USPTO interprets the "independent and distinct" language of the statute as "independent or distinct". See section 802.01 where it says:

> This raises the question of the subjects as between which the Commissioner may require restriction. This, in turn, depends on the construction of the expression "independent and distinct" inventions.
>
> "Independent", of course, means not dependent. If "distinct" means the same thing, then its use in the statute and in the rule is redundant. If "distinct" means something different, then the question arises as to what the difference in meaning between these two words may be. The hearings before the committees of Congress considering the codification of the patent laws indicate that 35 U.S.C. 121: "enacts as law existing practice with respect to division, at the same time introducing a number of changes."
>
> The report on the hearings does not mention as a change that is introduced, the subjects between which the Commissioner may properly require division.
>
> The term "independent" as already pointed out, means not dependent. A large number of subjects between which, prior to the 1952 Act, division had been proper, are dependent subjects, such as, for example, combination and a subcombination thereof; as process and apparatus used in the practice of the process; as composition and the process in which the composition is used; as process and the product made by such process, etc. If section 121 of the 1952 Act were intended to direct the Commissioner never to approve division between dependent inventions, the word "independent" would clearly have been used alone. If the Commissioner has authority or discretion to restrict independent inventions only, then restriction would be improper as between dependent inventions, e.g., the examples used for purpose of illustration above. Such was clearly not the intent of Congress. Nothing in the language of the statute and nothing in the hearings of the committees indicate any intent to change the substantive law on this subject. On the contrary, joinder of the term "distinct" with the term "independent", indicates lack of such intent. The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact, "distinct" inventions, even though dependent.

Furthermore, MPEP 803 says (emphasis added):

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 - §806.04(i)) **or** distinct (MPEP § 806.05 - § 806.05(i)).

Based on this interpretation of the statute, the restriction requirement is not improper merely because the examiner failed to demonstrate that the inventions are independent.

Petitioner also argued that even if the inventions only have to be distinct from each other for the restriction to be proper, in this case the inventions restricted from each other, a full length sequence and fragments and variants of the sequence, are related as combination and subcombination inventions. As such, two way distinctness is required. The petition puts it this way:

> The full-length claims and the fragment and variant claims are not "two-way" distinct. For example, if the polypeptide of the full-length claims (i.e., the combination) was known in the art before the invention of the polypeptides of the fragment and variant claims (the subcombination claims), the subcombinations would not be patentable as claimed. This is because the full-length sequence would anticipate the fragment and variant claims. Thus, the Examiner erred in concluding that claims 21-95 are patentably distinct.

To support this position, petitioner includes on page 5 of the petition a quote from the USPTO that discusses viewing genes and nucleic acids as being combinations of sequences that are subcombinations. See page 5 of the petition as well as Exhibit G of the petition.

This argument is also not persuasive. First, the quote used to support petitioner's position is not discussing restriction practice, it is discussing the issue of written description under 35 U.S.C. §112, first paragraph. In this context, combination/subcombination is being related to situations when an adequate written description is present and when it is not. Since the quote is referring to written description, not restriction, it would not be appropriate to rely upon this as support for petitioner's position here.

Second, it is not agreed that the inventions as claimed are really related as combination/subcombination. The MPEP defines a combination as "an organization of which a subcombination or element is a part". See MPEP 806.05(a). Take, for example, a couple of the inventions as claimed:

1. An isolated protein comprising a polypeptide having an amino acid sequence of amino acid residues 1 to 223 of SEQ ID NO:2.

2. An isolated protein comprising a polypeptide having an amino acid sequence of amino acid residues 1 to 173 of SEQ ID NO:2.

(Note, the numbers do not correspond to specific claims in this application but the inventions do correspond to specifically claimed inventions in this application.) Petitioner is essentially saying that 2 is a subcombination of 1. However, with the use of the term "comprising" in 2, that invention encompasses amino acid residues 1-173 of SEQ ID NO:2 plus anything else on the ends thereof. This would include many possibilities where the additional sequences beyond residue 173 do not match SEQ ID NO:2. Such sequences clearly would not be subcombinations of 1. Since the invention as a whole in 2 would encompass so many possibilities that could not

be construed as subcombinations of 1, then it is reasonable here to conclude that the invention as a whole in 2 is not related to the invention as a whole in 1 as combination/subcombination.

Third, even if the inventions were claimed using consisting of language for the fragment claims, the inventions still would not be related as combination/subcombination. Take, for example, the following:

1. An isolated protein comprising a polypeptide having an amino acid sequence of amino acid residues 1 to 223 of SEQ ID NO:2.

2. An isolated protein consisting of a polypeptide having an amino acid sequence of amino acid residues 1 to 173 of SEQ ID NO:2.

Since such proteins are chemical compounds, the invention of 2 would inherently include some terminal chemical moiety. In such a situation, the chemical compound would not be a subcombination of the full length protein but merely a separate chemical compound. Consider methane (CH_4) and toluene (C_6H_5-CH_3) as an analogous situation. It should be abundantly clear that methane and toluene are not related as combination/subcombination for restriction purposes but would merely be considered as distinct chemical entities that are appropriately restrictable from each other for examination purposes. If this is the case for methane and toluene, it should be the same for the inventions claimed as above and in this application. Therefore, the conclusion drawn by the examiner that each of the various proteins "represents a patentably distinct product with distinct physical and functional characteristics" is deemed valid and sufficient for restriction purposes.

Fourth, even if the inventions claimed in this application were related as combination/subcombination, restriction would still be appropriate here. The argument made by petitioner is not consistent with the standard for distinctness as set forth in the MPEP. The MPEP sets for the standard for distinctness for inventions related as combination/subcombination as follows:

> The inventions are distinct if it can be shown that a combination as claimed:
>
> (A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), and
>
> (B) the subcombination can be shown to have utility either by itself or in other and different relations.

In this case, the full length sequence as claimed does not require the particulars of the fragments for patentability because even if the fragments are known, the full length sequence may be patentable over the fragments due to the presence of different amino acid residues in areas of the full length sequence not covered by the fragments. Furthermore, the fragments can be shown to have utility either by itself or in other and different relations as evidenced by the claims specifically reciting the fragments by themselves and the disclosure that such fragments are useful apart from the combination.

For these reasons, it is hereby concluded that the restriction requirement as presented by the examiner is proper and, consequently, there is no reason to withdraw that restriction requirement.

PETITION DENIED.

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